

Application No.: 10/805,224

Docket No.: 21854-00019-US1

**REMARKS**

Receipt of the Office Action mailed March 2, 2005 is acknowledged. Claims 11-22 remain pending and have been rewritten so as to be all examinable in this single application. Claims 11-17 and 20-22 are now directed to biodegradable polymers and claims 18-19 are directed to their process of manufacture. Under the *In re Ochiai* guidelines, upon allowance of a product claim, the methods of manufacture should be rejoined therewith. Reconsideration of the application and early allowance is earnestly solicited.

**The Interview**

Applicants express their gratitude to the courtesy extended to their representatives during an interview on April 6, 2005. The content of the interview is accurately reflected on the interview summary record. The two cases that were brought to the interview were *In re Roemer* and *Ecolochem vs. Southern California*.

**The Office Action**

Claims 11, 16 and 17 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. It is respectfully submitted that in view of the present amendment, this rejection is now moot. Withdrawal of the rejection and favorable reconsideration are earnestly solicited.

Claims 11-15 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Mayer et al. (U.S. Patent 5,322,866) in view of Tomka (U.S. Patent 5,362,777) and Schiltz (US Patent No 5,449,708).

This rejection is respectfully traversed for at least the following reasons. Namely it is respectfully urged that there is simply no motivation in any of the references to prepare a biodegradable polymer as claimed. Namely, the Examiner admits that the primary reference Mayer does not mention modified starch and stearic acid as ingredients of its blend. For this teaching, the Examiner has relied upon Tomka and Schiltz. However, the instant claims recite specific percentages of each ingredient that are not taught or even suggested by Tomka or

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Schiltz. To wit, Mayer teaches use of PVOH or EVOH in an amount from 20-80%. However, the instant claims recite using a water soluble polymer in an amount from 4-11%. Where is the motivation to change what Mayer utilizes? What motivation is found in any of the secondary references to include at least about 8% of a modified starch in Mayer's composition? Mayer teaches that its composition is biodegradable as is, and there is simply no motivation to add in a modified starch, much less in the amount instantly recited.

With respect to adding stearic acid, the Examiner is apparently of the opinion that Mayer would have sought to increase gelatinization of starch to improve physical properties and hence, would have been motivated to add stearic acid in the amount instantly recited. Applicants respectfully disagree. On what basis is this conclusion made? There does not appear to be any teaching of the desirability of this feature found in any of the references being applied.

It is well established that obviousness under 103 cannot be predicated on the fact some proffered combination was "obvious to try." Namely, measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). One "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1780, 1783 (Fed. Cir. 1988).

The case law makes clear that the best defense against a hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. See Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617. "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight." Id.

"When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references." In re Rouffet, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) (citing In re Geiger, 815 F.2d 686, 688, 2

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USPQ2d 1276, 1278 (Fed. Cir. 1987)). "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). Although the suggestion to combine references may flow from the nature of the problem, see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), "[d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness," Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 880, 45 USPQ2d 1977, 1981 (Fed. Cir. 1998). Therefore, "[w]hen determining the patentability of a claimed invention which combines two known elements, 'the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.'" In re Beattie, 974 F.2d 1309, 1311-12, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) (quoting Lindemann, 730 F.2d at 1462, 221 USPQ at 488).

"The suggestion to combine may be found in explicit or implicit teachings within the references themselves, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved." WMS Gaming, Inc. v. International Game Tech., 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). *However, there still must be evidence that "a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed."* In re Rouffet, 149 F.3d at 1357, 47 USPQ2d at 1456; see also In re Werner Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000), emphasis supplied. ("[A] rejection cannot be predicated on the mere identification . . . of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.").

The idea that a patented invention might appear to be obvious given the excellent vision accorded by hindsight, but might not have been obvious at the time the invention was made, was discussed by the Supreme Court in Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). In the intervening years since Graham a great deal of attention has been paid to the importance of

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secondary considerations. The Supreme Court held that "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy." 383 U.S. at 17-18 (internal citations omitted).

Indeed, Applicant's claimed polymer is unexpectedly superior to other compositions. As mentioned during the interview, some polymers of the instant claims are capable of dissolving directly in water. There was no suggestion in any of the references being relied upon that by modifying the Mayer polymer, it would have been possible to create a polymer that dissolves in water. Moreover, the instant composition has been tremendously successful commercially. The Examiner is requested to review arguments and declarations submitted in the parent application, which arguments and declarations are incorporated herein by reference in their entireties.

Since Applicants have shown there is no teaching or suggestion in the proffered combination of references to prepare a biodegradable polymer as claimed, the instant rejection is improper and should be withdrawn.

In view of the above amendment, applicant believes the pending application is in condition for allowance. Should the Examiner wish to discuss this case or propose any suggestions for placing the application in more suitable form for allowance, the Examiner is invited to contact the office of the undersigned attorney of record.

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Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 22-0185, under Order No. 21854-00019-US1 from which the undersigned is authorized to draw.

Dated: April 15, 2005

Respectfully submitted,

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